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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,624	07/13/2000	Peter C. Brooks	13761-734	3563

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EXAMINER

NICKOL, GARY B

ART UNIT

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1642

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/615,624	<b>Applicant(s)</b> BROOKS ET AL.	
	<b>Examiner</b> Gary B. Nickol Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-104 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>fax cover sheet</i>        |

### **DETAILED ACTION**

Claims 1-104 are pending in the application and are currently under prosecution.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is accepting a Fax Response for Written Restriction Requirements. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 4-5, 7-17, 22-24, drawn to an antagonist that inhibits angiogenesis by modifying protein-protein interactions wherein the first protein is MMP-9 and the second protein is a  $\beta 1$ -containing integrin, classified in class 530, subclass 387.1.
- II. Claims 1, 3, 6, 8-17, 22-24, drawn to an antagonist that inhibits angiogenesis by modifying protein-protein interactions comprising  $\alpha 5\beta 1$ , classified in class 530, subclass 387.1.
- III. Claims 1-2, 4-5, 7-13, 19-21, drawn to an antagonist that inhibits angiogenesis by modifying protein-protein interactions wherein the first protein is MMP-9 and the second protein is a  $\beta 1$ -containing integrin, classified in class 536, subclass 22.1.

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- IV. Claims 1, 3, 6, 8-13, 19-21, drawn to an antagonist that inhibits angiogenesis by modifying protein-protein interactions comprising  $\alpha 5 \beta 1$ , classified in class 536, subclass 22.1.
- V. Claims 1-2, 4-5, 7-13, 18, drawn to an antagonist that inhibits angiogenesis by modifying protein-protein interactions wherein the first protein is MMP-9 and the second protein is a  $\beta 1$ -containing integrin, classified in class 530, subclass 300+.
- VI. Claims 1, 3, 6, 8-13, 18, drawn to an antagonist that inhibits angiogenesis by modifying protein-protein interactions comprising  $\alpha 5 \beta 1$ , classified in class 530, subclass 300+.
- VII. Claims 25-28, drawn to a polypeptide for inhibiting angiogenesis and or tumor growth that specifically binds MMP-9 with a binding affinity greater than the binding capacity of SEQ ID NO:3 to MMP-9, classified in class 514, subclass 2.
- VIII. Claims 25, 29-30, drawn to a monoclonal antibody for inhibiting angiogenesis and or tumor growth that specifically binds MMP-9 with a binding affinity greater than the binding capacity of SEQ ID NO:3 to MMP-9, classified in class 530, subclass 388.1.

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- IX. Claims 31-34, drawn to a polypeptide for inhibiting angiogenesis and or tumor growth that specifically binds a  $\beta$ 1-containing integrin with a binding affinity greater than the binding capacity of SEQ ID NO:3 to the  $\beta$ 1-containing integrin, classified in class 514, subclass 2.
- X. Claims 31, 35-36, drawn to a monoclonal antibody for inhibiting angiogenesis and or tumor growth that specifically binds a  $\beta$ 1-containing integrin with a binding affinity greater than the binding capacity of SEQ ID NO:3 to the  $\beta$ 1-containing integrin, classified in class 530, subclass 388.1.
- XI. Claims 37-42, drawn to an antagonist that specifically binds with SEQ ID NO:1, but also binds to SEQ ID NO:3 with reduced affinity, classified in class 514, subclass 2.
- XII. Claims 37-40, 43-44, drawn to a monoclonal antibody that specifically binds with SEQ ID NO:1, but also binds to SEQ ID NO:3 with reduced affinity, classified in class 530, subclass 388.1.
- XIII. Claims 45-50, drawn to a protein antagonist that disrupts the localization of MMP-9 on a cell surface or blood vessel, classified in class 530, subclass 300.

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- XIV. Claims 45-48, 51-52 drawn to a monoclonal antibody that disrupts the localization of MMP-9 on a cell surface or blood vessel, classified in class 530, subclass 388.1.
- XV. Claims 53-59, drawn to a method of inhibiting angiogenesis comprising administering an antagonist, classified in class 424, subclass 184.1.
- XVI. Claims 60-64, drawn to a method of inhibiting tumor growth comprising administering an antagonist, classified in class 424, subclass 184.1.
- XVII. Claims 65-68, drawn to a method of inhibiting psoriasis, macular degeneration, or restenosis in a tissue comprising administering an antagonist, classified in class 424, subclass 184.1.
- XVIII. Claims 69-72, drawn to a method of detecting angiogenesis in a tissue by contacting an antagonist with said tissue, classified in class 424, subclass 9.1.
- XIX. Claims 73-76, drawn to a method of detecting tumors or tumor invasion by administering an antagonist, classified in class 424, subclass 9.1.
- XX. Claims 77-80, 85-88, drawn to a method of screening for MMP-9 antagonists comprising providing a non-peptide antagonist and measuring said antagonist's

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affinity for binding with MMP9 and SEQ ID NO:3, classified in class 435, subclass 4.

XXI. Claims 77, 81, 85-88, drawn to a method of screening for MMP-9 antagonists comprising providing a peptide antagonist and measuring said antagonist's affinity for binding with MMP9 and SEQ ID NO:3, classified in class 435, subclass 4.

XXII. Claims 77, 82-88, drawn to a method of screening for MMP-9 antagonists comprising providing an antibody antagonist and measuring said antagonist's affinity for binding with MMP9 and SEQ ID NO:3, classified in class 435, subclass 7.1.

XXIII. Claims 89-92, 97-100 drawn to a method of screening for  $\beta$ 1 integrin antagonists comprising providing a non-peptide antagonist and measuring said antagonist's affinity for binding with a  $\beta$ 1 integrin and SEQ ID NO:3, classified in class 435, subclass 4.

XXIV. Claims 89, 93, 97-100 drawn to a method of screening for  $\beta$ 1 integrin antagonists comprising providing a peptide antagonist and measuring said antagonist's affinity for binding with a  $\beta$ 1 integrin and SEQ ID NO:3, classified in class 435, subclass 4.

XXV. Claims 89, 94-100 drawn to a method of screening for  $\beta 1$  integrin antagonists comprising providing an antibody antagonist and measuring said antagonist's affinity for binding with a  $\beta 1$  integrin and SEQ ID NO:3, classified in class 435, subclass 7.1.

XXVI. Claims 101-104, drawn to a peptide comprising a sequence encoding an epitope recognized by a monoclonal antibody, classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-XIV, XXVI represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups XV-XXV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Groups I-VI and the methods of Groups XV-XIX are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different



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process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antagonist product of Claim 1 can be used in a multitude of materially different process (i.e., detecting metastasis, inhibiting psoriasis, etc.,) with different objectives as identified and grouped above.

The invention of Groups I-XV, XXVI and the methods of Groups XX-XXV are not at all related because the products of Group I-XV, XXVI are not used in any of the methods of Groups XX-XXV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
August 20, 2002

